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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,736	11/14/2001	Richard Philpott	56066/45858	9454
21874	7590	07/13/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			GOLDBERG, JEANINE ANNE	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,736

Applicant(s)

PHILPOTT ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5,7-27 and 33-43 is/are pending in the application.
- 4a) Of the above claim(s) 5,33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4,7-27 and 35-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed May 13, 2004. Currently, claims 2-5, 7-27, 33-43 are pending. Claims 5, 33-34 are withdrawn from consideration. Claims 2-4, 7-27, 35-43 are currently under examination.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is FINAL.
3. Any objections and rejections not reiterated below are hereby withdrawn in view of the amendments to the claims or applicant's arguments.
 - a. The rejection over Staub et al. (US Pat. 6,187,540, February 2001) as evidenced by Gibco BRL Products Catalog (FTA Card, page 2-7, 1999) and Burgoyne (US Pat. 5,496,562, March 1996) has been withdrawn in view of the arguments. The response argues that the use of the buccal swab to collect saliva does not contain any upstream processing of a biological sample to produce a suspension comprising cells. Upon further consideration, the examiner agrees that there is no processing to produce a suspension which is then applied to the first solid medium. The suspension of saliva is not applied to the buccal swab. Claims 11 and 16 are similarly drawn such that there is no isolation of the cells from all the non-cellular components using a buccal swab.
4. This action contains new grounds of rejection necessitated by amendment.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1634

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Newly amended Claims 2-4, 7-27, 35-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A2) Claims 2-4, 7-27, 35-43 are indefinite over the recitation "comprises a dry solid medium" because it is unclear whether the second solid medium IS dry when it is contacted with the first solid medium or whether the second solid medium was at one point dry but also encompasses a medium which has been altered and is wet. The response appears to be arguing that the second solid medium is a dry solid medium when it is contacted with the first solid medium, however the claim is not clear either way. The rejection may be easily overcome by amending "contacting the cells on the first solid medium with a second solid medium wherein the second solid medium comprises a dry solid medium" to "contacting the cells on the first solid medium with a second solid medium wherein the second solid medium is a dry solid medium."

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

Art Unit: 1634

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 4, 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Kathariou et al. (US Pat. 6,503,747, January 2003) as evidenced by www-biology.ucsd.edu/labs/aroian/protocols/electroblot.htm.

Kathariou et al. (herein referred to as Kathariou) teaches a method for analyzing genetic material. Mutants from 96-well plates were inoculated with a 48 prong replicating device on agar plates (first solid medium) and grown overnight. Bacterial colonies were transferred onto nitrocellulose membranes (second solid mediums) presoaked in Towbin transfer buffer. The nitrocellulose membranes were dried and processed using immunoblot procedures (col. 18, lines 30-40)(limitations of Claim 7). The colonies were dissociated from the culture plates (limitations of Claim 4).

The art teaches Towbin transfer buffer is a solution of Tris, Glycine, SDS, MeOH at a pH of about 8.3. Towbin is considered a preserving means.

Response to Arguments

The response traverses the rejection. The response asserts that the claim has been amended to required that the second solid medium comprises a dry solid medium, such that the rejection has been overcome. The response argues that the membranes of Kathariou were wet with transfer buffer at the time of transfer and needed to be dried prior to processing (Response dated May 11, 2004, page 21). This argument has been reviewed but is not convincing because the claim limitation reads that the second solid medium comprises a dry solid medium. The claim does not require that the second

solid medium is dry when it is contacted with the first solid medium. The claim broadly encompasses a medium which was dry prior to apply the reagents, such that the second solid medium comprises a dry solid medium and liquid reagents. The examiner suggested claim language to applicant which would overcome the rejection of record, however, applicant indicated they would prefer an action in writing.

The response further asserts that it is not clear what "dissociating the cells of the biological sample" is referring to. With respect to Claim 4, the upstream processing of the biological sample includes the inoculation into wells, incubation, and dissociating the cells from the well plates to contact with the agar plates. The response appears as though they may be reading limitations into the claims which are not there. The claim states that the upstream processing step includes a dissociation of the cells of the biological sample. Kathariou teaches upstream processing which dissociates cells from the 96 well culture plates to place in suspension which is applied to the agar plates.

Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

7. **No claims allowable.**

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeanine Goldberg

Patent Examiner

July 12, 2004